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Disposable surgical face masks for preventing surgical wound infection in clean surgery

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Abstract

Available in English | Español | Français

Background

Surgical face masks were originally developed to contain and filter droplets containing microorganisms expelled from the mouth and nasopharynx of healthcare workers during surgery, thereby providing protection for the patient. However, there are several ways in which surgical face masks could potentially contribute to contamination of the surgical wound, e.g. by incorrect wear or by leaking air from the side of the mask due to poor string tension.

Objectives

To determine whether the wearing of disposable surgical face masks by the surgical team during clean surgery reduces postoperative surgical wound infection.

Search methods

In December 2015, for this seventh update, we searched: The Cochrane Wounds Specialised Register; The Cochrane Central Register of Controlled Trials; Ovid MEDLINE; Ovid MEDLINE (In-Process & Other Non-Indexed Citations); Ovid EMBASE and EBSCO CINAHL. We also searched the bibliographies of all retrieved and relevant publications. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria

Randomised controlled trials (RCTs) and quasi-randomised controlled trials comparing the use of disposable surgical masks with the use of no mask.

Data collection and analysis

Two review authors extracted data independently.

Main results

We included three trials, involving a total of 2106 participants. There was no statistically significant difference in infection rates between the masked and unmasked group in any of the trials. We identified no new trials for this latest update.

Authors' conclusions

From the limited results it is unclear whether the wearing of surgical face masks by members of the surgical team has any impact on surgical wound infection rates for patients undergoing clean surgery.

Plain language summary

Available in English | Deutsch | Español | Français | Hrvatski | Русский

Disposable surgical face masks for preventing surgical wound infection in clean surgery

Background

Surgeons and nurses performing clean surgery wear disposable face masks. The purpose of face masks is thought to be two-fold: to prevent the passage of germs from the surgeon's nose and mouth into the patient's wound and to protect the surgeon's face from sprays and splashes from the patient. Face masks are thought to make wound infections after surgery less likely. However, incorrectly worn masks may increase the likelihood of the wound getting contaminated with germs. We wanted to discover whether wearing a face mask during surgery makes infections of the wound more likely after the operation.

Review question

This review aimed to find out if wearing disposable face masks increases or decreases the number of cases of wound infection after clean surgery.

Study characteristics

We searched for all studies that had been done in the past relevant to this topic. Studies included in our analysis were those looking at the use of face masks in 'clean' surgery in adults and children. Clean surgery is when the operation does not go into organs that may contain bugs such as the lungs, gut, genitals and bladder. Infections of the wound are less likely to occur after 'clean' surgery, compared to 'unclean' surgery. We chose to look at this type of surgery because

infections occurring after clean surgery would more likely be due to the use of the face mask, and not because of the nature of the operation. We also only looked at one particular type of study, the randomised controlled trial (RCT), where the people involved (participants) were randomly put into one of two groups: one group where the surgical team wore a face mask during the operation and one group where the surgical team did not wear a face mask. We compared the number of wound infection cases occurring after surgery between two groups.

Key results

Overall, we found very few studies and identified no new trials for this latest update. We analysed a total of 2106 participants from the three studies we found. All three studies showed that wearing a face mask during surgery neither increases nor decreases the number of wound infections occurring after surgery. We conclude that there is no clear evidence that wearing disposable face masks affects the likelihood of wound infections developing after surgery.

Quality of the evidence

The findings from this review cannot be generalised for several reasons: the studies included only looked at clean surgery, some of the studies did not specify what type of face mask was used and one of the studies did not involve many participants therefore making the findings less credible. The quality of the studies we found was low overall. The way in which participants were selected for the studies was not always completely random, which means the authors' judgements could have influenced the results. More research in this field is needed before making further conclusions about the use of face masks in surgery.

This plain language summary is up to date as of 22nd December 2015.

Authors' conclusions

Implications for practice

From the limited results, it is unclear whether the wearing of surgical face masks by the surgical team either increases or reduces the risk of surgical site infection in patients undergoing clean surgery.

Implications for research

Important messages for future research:

1. The CONSORT statement should be used as a guideline for reporting of future trials (Schulz 2010).
2. Trials should be large enough to detect clinically important differences in infection rates.
3. Trials must discriminate between scrubbed and non-scrubbed personnel.
4. Trials must include clear definitions of surgery, surgical face masks and surgical wound infection.
5. Randomisation should be 'per operating list' (cluster randomisation) rather than 'per case' to avoid potential

contamination of the surgical environment. To guard against selection bias, the randomisation allocation should be unpredictable, concealed and take place immediately prior to the commencement of the operating list.

6. Follow-up should be appropriate to the surgery performed. This may extend to the involvement of primary care.
7. Outcome assessors should be blinded to allocation.
8. Analysis should be by intention-to-treat of all patients following randomisation.
9. Economic evaluations should be incorporated into future trials.

Areas for further investigation include:

- disposable surgical face mask compared with wearing no mask;
- disposable surgical face mask compared with other mechanisms for protecting both patients and staff, such as visors/helmets.

Background

Description of the condition

Surgical face masks were originally developed to contain and filter droplets containing microorganisms expelled from the mouth and nasopharynx during surgery. They were introduced around a century ago as a method of protecting patients from the risk of surgical wound infections (Belkin 1997). The costs incurred when a patient contracts a surgical wound infection are considerable in financial as well as social terms. It has been estimated that each patient with a surgical wound infection requires an additional hospital stay of 6.5 days and that hospital costs are doubled (Plowman 2000). When extrapolated to all acute hospitals in England, it is estimated that the annual cost nationally is almost GBP 1 billion.

Description of the intervention

The primary purpose of a surgical mask is to provide protection for the patient from the surgical team. Masks have also been advocated as a barrier to protect the surgical team from the patient (Garner 1996; Weber 1993). This systematic review does not investigate the use of surgical masks for this purpose.

Surgical face masks are disposable and generally made up of three or four layers, often with two filters that prevent passage of material greater than 1 micron, therefore trapping bacteria of that size or larger. Face masks of this type are claimed to provide protection for a minimum of four hours (UHS 2000). Worn correctly, the mask should cover the nose with the metal band contouring the bridge of the nose. The mask should be drawn underneath the mouth and secured by tying the tapes firmly around the back of the head.

Although the surgical mask is designed to protect the patient, there are several ways in which it could actually contribute to the contamination of surgical wounds. Firstly, insufficient tension on the strings causes 'venting', or

leakage of air from the side of the mask. The exhalation of moist air increases resistance, which is thought to exacerbate the problem of venting (Belkin 1996). Secondly, Belkin 1996 also cites 'wicking' as a method of conveying liquid via capillary action as possibly contributing to the passage of bacteria. Thirdly, a mask could cause contamination by 'wiggling'. This is a term used to describe friction of the mask against the face, which has been shown to cause the dispersal of skin scales from the face resulting in possible contamination of surgical wounds (Schweizer 1976). In addition, the mask may be worn incorrectly, for example, allowing exposure of the nose or mouth. Removal of the mask by grasping the filter section could result in contamination of the wearer's hands whereas disposal is recommended by handling the tapes only (Perry 1994).

How the intervention might work

These issues call into question the effectiveness of the design and highlight the incorrect use of surgical face masks. As with many interventions, surgical face masks were introduced without standard specifications or formal evaluation. Despite acknowledging the controversy surrounding the use of masks, they are currently recommended by numerous operating department organisations (AORN 1998; AfPP 2007).

There is evidence that face mask practice is inconsistent, possibly due to an inadequate rationale for their use. For example, the use of surgical face masks has been abandoned by some surgical teams (in part or whole) and during certain procedures. In choosing to not wear a mask, members of the surgical team could be leaving the patient vulnerable to the risk of wound infection via droplet contamination.

A clean surgical wound is classified as "an uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital or uninfected urinary tract is not entered" (Mangram 1999). Non-clean wounds may be classified as clean-contaminated, contaminated or dirty-infected, depending upon the area of the body operated upon and the level of infection and inflammation present. A surgical wound is less likely to become infected postoperatively if it is classified as clean, therefore any infection arising could be more reasonably attributed to other factors such as the use of a surgical face mask (Mangram 1999).

Diagnosis of a surgical wound infection is not without its challenges. For example, some patients such as the elderly and the immunocompromised do not always display the cardinal signs of infection. However, correct diagnosis of surgical wound infections is imperative to ensure accurate surveillance. A surgical wound infection is defined by purulent drainage and at least one of the following signs or symptoms: pain, localised swelling, redness or heat (Mangram 1999).

Why it is important to do this review

The above discussion indicates that the role of the surgical mask as an effective measure in preventing surgical wound infections is questionable and warrants a systematic review.

Objectives

To determine whether the wearing of disposable surgical face masks by the surgical team during clean surgery reduces

postoperative surgical wound infection.

Methods

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and quasi-randomised controlled trials comparing the use, by members of the surgical team, of disposable surgical masks with the use of no mask.

Types of participants

Adults and children undergoing clean surgery.

Types of interventions

The specific comparison to be made is the wearing, by the surgical team (scrubbed and not scrubbed), of disposable surgical face masks compared with no masks. Due to the difference in specifications, we used the trial author's definition of disposable surgical mask.

Types of outcome measures

Primary outcomes

- The incidence of postoperative surgical wound infection (the definition of wound infection used by the trial authors is used throughout).

Secondary outcomes

- Costs.
- Length of hospital stay.
- Mortality rate.

Publication date, language and publication status did not influence eligibility decisions.

Search methods for identification of studies

Electronic searches

For this seventh update, we searched the following databases to identify reports of relevant clinical trials:

- The Cochrane Wounds Specialised Register (searched 22 December 2015);
- The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2015, Issue 11);
- Ovid MEDLINE (1946 to 22 December 2015);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations) (searched 22 December 2015);
- Ovid EMBASE (1974 to 22 December 2015);
- EBSCO CINAHL Plus (1937 to 23 December 2015).

The search strategies used for these databases can be found Appendix 1. We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version; Ovid format (Lefebvre 2011). We combined the EMBASE search with the Ovid EMBASE trial filter terms developed by the UK Cochrane Centre (Lefebvre 2011). We combined the CINAHL searches with the trial filter terms developed by the Scottish Intercollegiate Guidelines Network (SIGN 2015).There were no restrictions with respect to language, date of publication or study setting.

Searching other resources

We searched the bibliographies of all retrieved and relevant publications identified by these strategies for further studies.

Data collection and analysis

Selection of studies

Two review authors independently assessed titles and abstracts of references identified by the search strategy according to the selection criteria. We obtained copies of those articles and studies that appeared to satisfy these criteria in full. When it was unclear from the title or abstract if the paper fulfilled the criteria, or when there was disparity between the review authors, we obtained a full-text copy. The two review authors jointly decided whether the study met the inclusion criteria. For this update, one review author assessed titles and abstracts of references identified by the search strategy. Again, when it was unclear from the title or abstract if the study fulfilled the criteria, the full-text was obtained and reviewed by one review author, all decisions were discussed with a member of the editorial team of Cochrane Wounds.

Data extraction and management

We used a piloted data extraction sheet to extract and summarise details of the studies. When data were missing from the study, we attempted to contact the trial authors to obtain missing information. Data extraction was undertaken independently by the two review authors and compared. We excluded studies if they were not randomised or quasi-randomised trials of disposable surgical face masks. Excluded studies are listed in the Characteristics of excluded studies table with reasons for their exclusion.

We extracted the following data from each study.

- Trial setting.

- Number of air filtration changes in the surgical field per hour.
- Filtering capacity/specification of masks.
- Types of surgery.
- Number of wound infections.
- Definition of wound infection.
- Depth of wound infection.
- Documentation of co-interventions.
- Use of prophylactic antibiotics.
- Use of antiseptic irrigation.
- Identified bacteria associated with staff and patients.
- Measurement of compliance in the wearing of surgical face masks (i.e. mask covered nose and mouth, presence of wicking and venting).
- The size of the surgical team.

Assessment of risk of bias in included studies

Two review authors independently assessed each included study using the Cochrane tool for assessing risk of bias (Higgins 2011). This tool addresses six specific domains, namely sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues (e.g. extreme baseline imbalance) (see Appendix 2 for details of the criteria on which each judgement was based). We assessed the studies to detect potential sources of bias in the study design. We extracted data regarding the following aspects of risk of bias.

- Method of randomisation: how the randomisation schedule was generated, the method of randomisation, e.g. envelopes, computer etc.
- Allocation concealment.
- Blinding of patients (recipients).
- Blinding of outcome assessors to wearing of masks.
- Extent of loss to follow-up and use of intention-to-treat analysis.
- Source of funding.
- Early stopping.
- Baseline comparability of treatment and control groups.

Data synthesis

We entered data into the Cochrane Review Manager (RevMan) software (RevMan 2014). Results are presented with 95%

confidence intervals (CI). Methods of synthesising studies were dependent upon the quality, design and heterogeneity of the studies identified. We reported estimates for dichotomous outcomes as odds ratio (OR) as the event rate was less than 30% (Altman 1991). Where synthesis was inappropriate, we undertook a narrative overview.

Results

Description of studies

Results of the search

The initial search, for the original review, yielded 250 citations; we examined the abstracts of these papers to assess potential relevance. We subsequently retrieved 97 papers for fuller examination. Of these, 84 were clearly not relevant to the review and 13 appeared potentially relevant. We subsequently excluded 11 from the review due to study design, or ineligible outcome measures (e.g. bacterial load). We included two studies. We identified no unpublished studies that met the criteria for inclusion. There was no response to requests for further information from the authors of two included studies (Chamberlain 1984; Tunevall 1991). No studies were published in duplicate. During subsequent updates of the review, we identified five further studies; four did not meet the inclusion criteria after assessment (Alwitry 2002; McGovern 2013; Salassa 2014; Sjol 2002), and one met the criteria for inclusion and we added it to the review (Webster 2010). We identified no new trials for this latest update.

This review took at face value any description in the original studies of the type and cleanliness category of surgery performed. In one study, we contacted the author who provided data for clean surgery only (Webster 2010). As a result, we included studies performed in the operating department and excluded other areas such as the laboratory, maternity ward and accident and emergency.

Included studies

See the Characteristics of included studies table.

Type of surgery

Tunevall 1991 included all types of surgery: clean, clean-contaminated and contaminated. Chamberlain 1984 involved gynaecological operation lists carried out by masked and unmasked staff. Webster 2010 randomised non-scrubbed staff per list into masked and unmasked groups. Surgery included obstetrics, gynaecology, general, orthopaedics, breast and urological. We only extracted data relating to clean surgery from all three studies.

Type of mask

Only one study specified the types of face mask used (Tunevall 1991), which were Comfort Clinimask (Molnycke), Surgine II antifog mask (Surgikos) and Aseptex (3M). In one study the type of mask was not mentioned (Chamberlain 1984), and in the other study standard masks were used (Webster 2010).

Number of patients

A power calculation informed Tunevall 1991 that their study would have to include over 3000 patients to demonstrate a decrease of 30% in the wound infection rate. It is unclear whether the power calculation took account of the clustered nature of the data. Although the Tunevall's study involved a total of 3088 patients, only 1429 patients undergoing clean surgery met the criteria for this review. In the study by Chamberlain 1984 only 41 patients were recruited because the study was discontinued. Out of this number, only 24 cases were clean surgery. With such a small number of female patients in this study, it is unlikely that they were representative of the population. Webster 2010 calculated that a sample size of at least 450 in each arm of the study would be needed to detect a 40% difference in surgical site infection rate between the two groups. Although 827 enrolled on the study, only 653 patients undergoing clean surgery met the criteria for this review (communication with trial author).

Outcome measures

The outcome measure used in Tunevall 1991 was wound infection defined as pus visible to the naked eye, or cellulitis without pus, both requiring debridement or percutaneous drainage and/or antibiotic therapy. With this study, follow-up was until after discharge but it was not explicit how these patients were followed up once discharged. Chamberlain 1984 did not define wound infection, but two out of the three wound infections reported were noted as serious enough to warrant antibiotics, the other infection being identified by a high vaginal swab. All patients in this study were examined daily until discharge. Webster 2010 used the National Nosocomial Infection Surveillance system, which categorises surgical site infections as superficial incisional, deep incisional and organ space. Follow-up was up to six weeks with the mean being 33.4 days for both groups.

None of the studies took any steps to measure compliance in relation to the correct wearing of surgical face masks, or recorded any events such as venting, wicking or wiggling. No study considered the other secondary outcome measures listed in this review.

Consent

One study author specified that consent was obtained from the staff involved in the study (Webster 2010). Tunevall 1991 stated that consent was obtained from patients, but Chamberlain 1984 and Webster 2010 did not specify that consent from patients had been obtained.

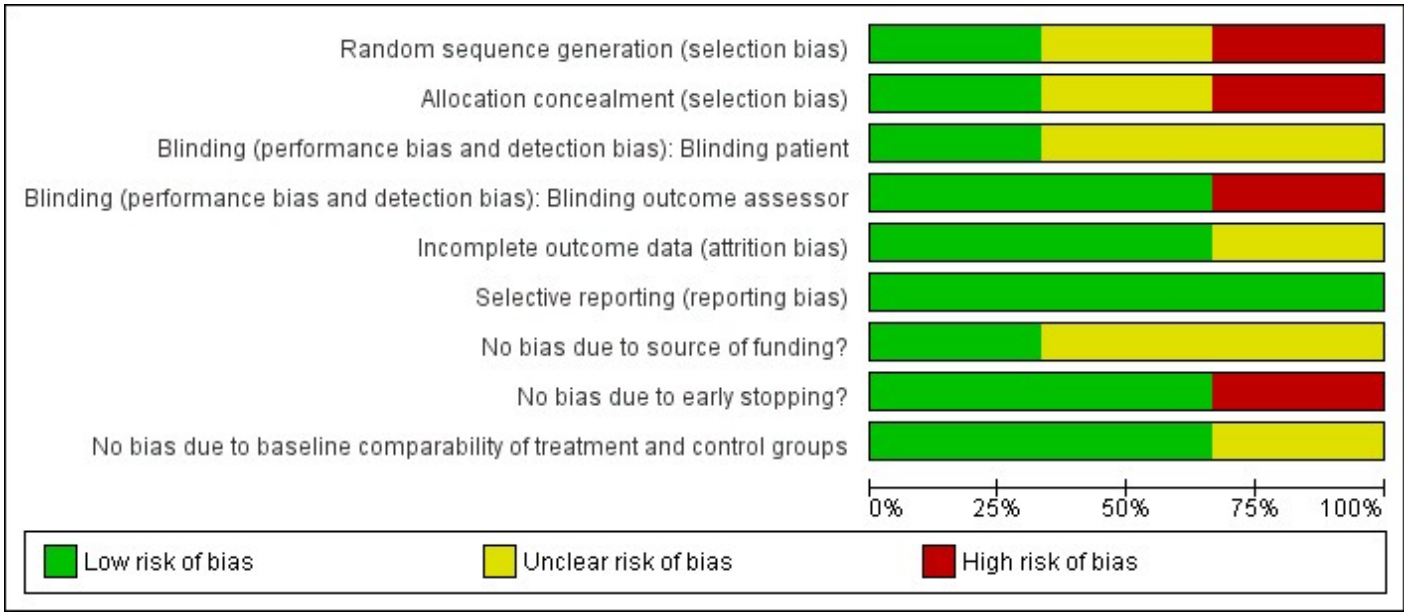
Excluded studies

We added a total of 15 studies to the Characteristics of excluded studies table. In summary, we excluded six studies because the focus of the study was not on assessing the rate of surgical site infection (Alwitry 2002; Ha'eri 1980; McGovern 2013; Norman 1995; Ritter 1975; Tunevall 1991). We excluded two studies because variables in addition to the rate of surgical site infection and the use of face masks were investigated (Berger 1993; Ruthman 1984). We excluded three studies because they did not involve any surgery and, rather, were simulation-based (Hubble 1996; McLure 1998; Mitchell 1991). Two studies were not RCTs or quasi-RCTs (Salassa 2014; Sjol 2002), one study assessed surgical site infection through the means of a patient questionnaire (Moore 2001), and one study did not state how many clean operations were included in their study (Orr 1981).

Risk of bias in included studies

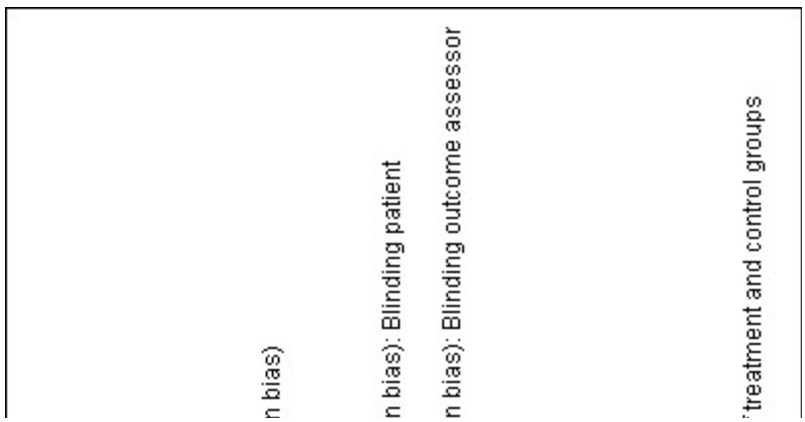
See Figure 1 for the graph showing the review author's judgements about each 'Risk of bias' item presented as percentages across all included studies. See also Figure 2 for the summary showing the review author's judgements about each 'Risk of bias' item

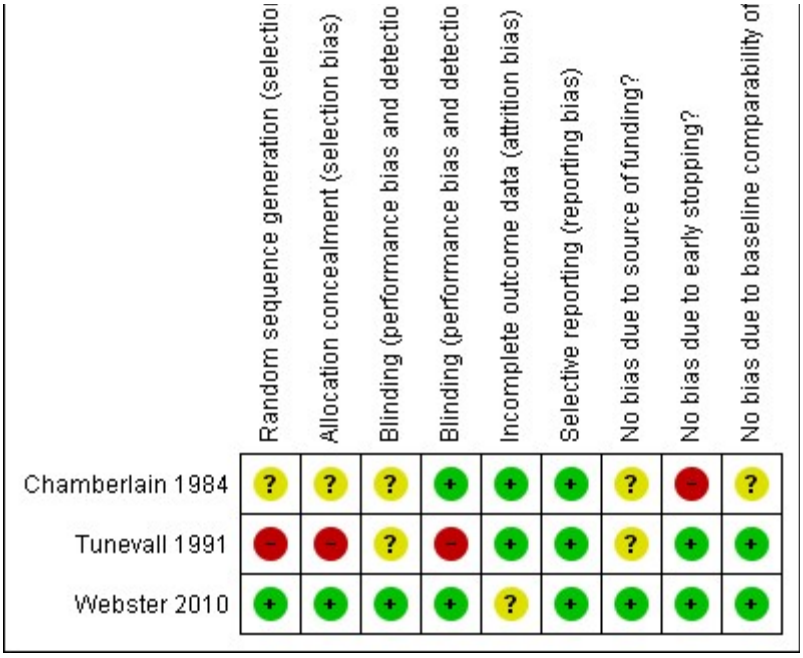
Figure 1 **Open in figure viewer**


Random sequence generation (selection bias)
Allocation concealment (selection bias)
Blinding (performance bias and detection bias): Blinding patient
Blinding (performance bias and detection bias): Blinding outcome assessor
Incomplete outcome data (attrition bias)
Selective reporting (reporting bias)
No bias due to source of funding?
No bias due to early stopping?
No bias due to baseline comparability of treatment and control groups
0%
25%
50%
75%
100%
Low risk of bias
Unclear risk of bias
High risk of bias

Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.

Figure 2 **Open in figure viewer**

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Selective reporting (reporting bias)
No bias due to source of funding?
No bias due to early stopping?
No bias due to baseline comparability of
Chamberlain 1984
Tunevall 1991
Webster 2010

Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

Allocation

Neither Chamberlain 1984 nor Tunevall 1991 used true randomisation with allocation concealment. Tunevall 1991 set up a random list for one year at a time denoting weeks as masked or unmasked but did not describe the method by which weeks were randomised to be masked/unmasked. A week, rather than an operating list or single operation, was the unit of allocation chosen for a period of one year, to ensure a similar number of major and minor cases (most major cases were performed at the beginning of the week). The randomisation list was inversed for the second and part of the third year due to anticipated seasonal differences. Allocation was not concealed as members of the theatre team were able to calculate whether any week was likely to be masked or unmasked. It is not clear whether the members of the admitting personnel had access to the randomisation list.

Chamberlain 1984 stated that patients on the operating lists of one surgical team were randomly allocated to a masked or unmasked group over two months. Later he indicated that masked and unmasked staff carried out the gynaecological operation lists alternately. The time between allocation of each list as masked or unmasked and the start of the list is not stated, making the extent of allocation concealment unclear.

Webster 2010 randomised participants per operating list. Allocation was concealed as randomisation occurred immediately before the start of the operating list via a phone call to a person blinded to the type of list.

In all studies the surgical team was the unit of randomisation and the patient was the unit of assessment, thus creating a unit of analysis error. There is no information in any study as to how patients were allocated to particular operating lists and so selection bias cannot be excluded.

Blinding

It was impossible to blind the care providers of the trials to wearing or omitting a surgical face mask. The blinding of patients was described by Webster 2010 but not by either Chamberlain 1984 or Tunevall 1991. No study distinguished between the use of local anaesthetic and general anaesthetic. Blinding of outcome assessors was achieved for Chamberlain 1984, where members of laboratory staff were unaware of the group allocation of the specimens obtained. Outcome assessors were also blinded in Webster 2010, where details of surgical site infections were obtained via routine surveillance or staff blinded to the intervention. In Tunevall 1991, specific notification of the trial was given with each wound swab submitted for culture, allowing the potential for detection bias.

Two studies included all members of the surgical team and neither of those studies examined whether particular members of the team were more or less likely to cause a surgical wound infection (Chamberlain 1984; Tunevall 1991). One study included only non-scrubbed staff (Webster 2010).

Incomplete outcome data

Chamberlain 1984 and Tunevall 1991 did not undertake an intention-to-treat analysis. Webster 2010 performed an intention-to-treat analysis. Chamberlain 1984 was discontinued after seven weeks after a third case of postoperative infection in the unmasked group was diagnosed. However the trial authors acknowledged that, although two of three wounds grew *Staphylococcus aureus*, in neither case was it a strain that corresponded to those isolated from the staff. No drop-outs were reported in Tunevall 1991. Webster 2010 reported seven drop-outs for clean surgery.

Other potential sources of bias

Source of funding

Two studies did not state a source of funding (Chamberlain 1984; Tunevall 1991), and one study declared a grant from Queensland Health Nursing Research (Webster 2010).

Early stopping of trial

Chamberlain 1984 was discontinued after seven weeks after a third case of postoperative infection in the unmasked group was diagnosed; this may well have been a chance difference, so potentially biasing the results in favour of masking.

Baseline imbalance

A description of the baseline characteristics of the patients is important to decide whether the results are generalisable and to compare characteristics of the two groups to ensure that the randomisation was successful. Tunevall 1991 confirmed baseline comparability for age and types of surgery. All patients in Chamberlain 1984 were female undergoing gynaecological surgery; no baseline comparability was reported. Groups were similar at baseline in Webster 2010 in terms of surgery, wound and American Society of Anaesthesiologists (ASA) classification as well as age, gender, preoperative hospitalisation, weight and prophylactic antibiotics.

Effects of interventions

The included studies compared the use of disposable surgical face masks with using no surgical face masks. A total of 2106 patients, undergoing clean surgery, were included in this review. We assessed clinical and methodological homogeneity. The observed clinical heterogeneity between the trials was reflected in parameters such as study population, time lapse between the first and latest study influencing technique and equipment, diagnosis and length of follow-up. Potential sources of clinical heterogeneity could be attributed to type of disposable surgical face mask, restricting non-scrubbed staff to the intervention group, operating theatre design (e.g. air flow rates) and country of study. Given this clinical heterogeneity, it was inappropriate to pool any of the studies.

Primary outcome: incidence of postoperative surgical wound infection

There were 2106 participants in three trials. Tunevall 1991 reported 13/706 (1.8%) postoperative wound infections in the masked group and 10/723 (1.4%) in the non-masked group (no statistically significant difference: odds ratio (OR) 1.34, 95% confidence interval (CI) 0.58 to 3.07). Chamberlain 1984 reported no postoperative wound infections in the masked group and 3/10 (30%) in the non-masked group (no statistically significant difference: OR 0.07, 95% CI 0.00 to 1.63). Webster 2010 reported 33/313 (10.5%) in the masked group and 31/340 (9.1%) in the non-masked group (no statistically significant difference: OR 1.17, 95% CI 0.70 to 1.97) (Analysis 1.1).

Secondary outcomes

None of the studies considered the secondary outcome measures specified in the review, i.e. costs, length of hospital stay and mortality rate.

Discussion

Given the widespread use of surgical face masks, research into this topic remains surprisingly neglected. It was disappointing that only two trials met the inclusion criteria for the original review and these were undertaken prior to 1991. The inclusion of a more recent trial has helped to address the lack of evidence (Webster 2010).

Much of current national and international policy is based upon equivocal evidence from laboratory studies of the filtration efficiency of surgical face masks and of potential contamination of the surgical field using settle plates. Such indirect evidence is of questionable clinical relevance.

Potential biases in the primary studies and the limitations they place on inferences

The strength of the evidence provided by the three studies that met the inclusion criteria for this review was weak. Two studies were quasi-randomised with unclear allocation concealment.

Methodologically, the results of Chamberlain 1984 and Tunevall 1991 may have been biased in several ways.

Chamberlain 1984 did not specify the criteria used to detect the presence of a wound infection. Mangram 1999 reports that failure to use objective criteria to define surgical site infection has been shown to substantially affect reported surgical site infection rates. Chamberlain 1984 was limited by the discontinuation of the trial after seven weeks as result of several infections, thus creating a potential bias in the findings towards the use of surgical face masks.

Follow-up in Chamberlain 1984 continued until after discharge and up to discharge in Tunevall 1991. However the actual duration of follow-up could have varied considerably depending upon the type of surgery performed, with the potential for underestimating the number of surgical wound infections. Follow-up in Webster 2010 was more in keeping with international guidance of 30 days, but in some cases was less. It is likely that the inadequate allocation concealment and lack of blinding in the Chamberlain 1984 and Tunevall 1991 studies could have resulted in under or over-estimation of the effects of wearing a surgical face mask.

We were surprised at the small number of published studies. This could be due to a reluctance on the part of researchers to submit an equivocal trial for publication, and in turn for it to be accepted for publication. However, publication bias could not be tested by a funnel plot due to the small number of included studies.

Potential biases in the review and the limitations it places on inferences

We relied on the goodwill of experts in the field to provide information on completed or ongoing, published or unpublished studies. When critically appraising the validity of the studies we had to rely on adequate reporting of the trials. When there is minimal information in the trial report one cannot automatically assume that rigorous methods have not been followed. We attempted to obtain additional clarifying data from the investigators of two studies, however no responses were received. Webster 2010 provided data on patients undergoing clean surgery.

The examination of the effectiveness of disposable surgical face masks must be seen in the context of the number of variables associated with wound infections. It is difficult to interpret from small studies, such as Chamberlain 1984, whether the wearing of surgical face masks has an impact on rates of surgical wound infections in patients undergoing clean surgery.

Applicability of results

The results extracted for this review were limited to clean surgery and therefore cannot be extrapolated to other categories of surgery. The contribution that disposable surgical face masks make towards preventing infection is likely to be less consequential in contaminated wounds than in clean surgery.

The types of disposable surgical face mask used in the study were specified by Tunevall 1991 but not by Chamberlain 1984 or Webster 2010. It is possible that the specific mask composition changed in the years spanning the studies and this has the potential to influence results.

Although the review did not exclude trials involving the implantation of prostheses, we found no trials of this nature therefore limiting application of the review's results to this type of surgery. One study, Webster 2010, differentiated between scrubbed and non-scrubbed members of the team but, because only non-scrubbed staff were randomised into the study, it was not possible to discriminate between the contribution of the scrubbed and non-scrubbed members of the surgical team to any resulting surgical wound infection. It could be argued that non-scrubbed members of the team

are less likely to be in a position to contaminate the surgical site.

All included studies were based in the operating department and so application of the results to other invasive procedures in other clinical areas is limited.

We examined the potential for surgical face masks to benefit the patient by reducing surgical wound infections or to harm the patient by increasing surgical wound infections in this review. We did not undertake analysis of the potential to harm or benefit the surgical team by way of protection. Although Chamberlain 1984 favoured the use of surgical face masks, the trial was relatively small and was discontinued due to the identification of wound infections in three out of the five major clean cases performed. This may have been a chance finding and thus these results are potentially biased in favour of wearing masks. Tunevall 1991 and Webster 2010 were larger trials, more rigorously designed and did not detect differences in the infection rate.

Both national and international guidelines acknowledge the controversy surrounding the use of disposable surgical face masks and yet continue to recommend their use. We found no other reviews in this area and the limited number of trials in this review make it unsafe to draw definitive conclusions about the effect of surgical face masks on reducing surgical wound infection in clean surgery.

References

References to studies included in this review

Jump to: **excluded studies** | **additional references** | **other published versions**

Chamberlain 1984 {published data only}

Chamberlain G, Houang E. Trial of the use of masks in the gynaecological operating theatre. *Annals of the Royal College of Surgeons of England* 1984;66(6):432-3.

PubMed | **Google Scholar**

Tunevall 1991 {published data only}

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Jump to: included studies | excluded studies | additional references

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Google Scholar

Characteristics of studies

Characteristics of included studies [ordered by study ID]

Jump to: scolaris.cdsr.references.jump.to.excluded.studies

Chamberlain 1984

Methods	Quasi-randomised controlled trial
Participants	41 female patients undergoing surgery; 24 clean and 17 non-clean Inclusion criteria: gynaecology Exclusion criteria: none stated Baseline comparability; none reported
Interventions	Group 1. Mask (n = 14) Group 2. No mask (n = 10)
Outcomes	Wound infection defined as serious enough to warrant antibiotics in 2 of the cases and via a high vaginal swab in the third case. Follow-up until discharge only.
Notes	Study discontinued due to 3 surgical wound infections in the unmasked group, although not proven as causal. Data extracted for clean surgery only. Unit of analysis error present.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomly allocated per list, but method unclear
Allocation concealment (selection bias)	Unclear risk	Time between allocation of masked and unmasked list and the list start was unclear
Blinding (performance bias and detection bias) Blinding patient	Unclear risk	Not described
Blinding (performance bias and detection bias) Blinding outcome assessor	Low risk	Quote: "The laboratory work was carried out by a member of staff who was not aware of the group allocation of the specimens obtained." Comment: blinding of outcomes assessors reduces risk of performance and detection bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intention-to-treat analysis not stated. No drop-outs reported.
Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported on, but trial protocol not accessed
No bias due to source of funding?	Unclear risk	No funding sources stated
No bias due to early stopping?	High risk	The study was discontinued after the third case of postoperative infection in the unmasked group. The study authors state that the bacterial strain of the infections did not correspond to those isolated from the staff.
No bias due to baseline comparability of treatment and control groups	Unclear risk	Baseline comparability not stated. All participants were female undergoing gynaecological surgery.

Tunevall 1991

Methods	Quasi-randomised controlled trial

Participants	3088 patients undergoing general, vascular, breast, acute and elective surgery. Clean surgery was performed on 1429. Non-clean surgery was performed on 1659. Trial setting: operating department. Inclusion criteria: operation through intact skin and primary closure. Exclusion criteria: patients not informed or consent not given; outpatients; orthopaedics; urology; anal surgery; insertion of synthetic grafts; or haematologic disease. Baseline comparability: similar for age, acute and cold surgery.
Interventions	Group 1. Mask (n = 706) Group 2. No mask (n = 723)
Outcomes	Wound infection defined as visible pus and/or cellulitis without pus requiring debridement, drainage and/or antibiotics. Duration of follow-up not stated but until after discharge from the ward.
Notes	Data extracted for clean surgery only. Patients had 2 to 3 body washes pre-operatively with 4% chlorhexidine prior to elective surgery. In most acute cases, at least one body wash was given. Unit of analysis error present.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Quote: "A random list was set up for 1 year, denoting weeks as 'masked' or 'unmasked'. To avoid seasonal differences between the groups the list was inversed for the second and for the third part of the year." Comment: this makes selection at high risk of bias
Allocation concealment (selection bias)	High risk	Inadequate as investigators enrolling participants could possibly foresee allocation and thus introduce selection bias
Blinding (performance bias and detection bias) Blinding patient	Unclear risk	Not described
Blinding (performance bias and detection bias) Blinding outcome assessor	High risk	Notification of the trial was issued with each wound swab
Incomplete outcome data (attrition bias) All outcomes	Low risk	Not analysed on an intention-to-treat basis. No drop-outs reported.

Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported on, but trial protocol not accessed
No bias due to source of funding?	Unclear risk	No funding sources stated
No bias due to early stopping?	Low risk	The trial was based on a power calculation and was not stopped early
No bias due to baseline comparability of treatment and control groups	Low risk	Baseline comparability stated for age and type of surgery

Webster 2010

Methods	Randomised controlled trial
Participants	811 patients undergoing gynaecological, obstetric, general (open), general (laparoscopic), urology and breast surgery. Clean surgery was performed on 660 patients and non-clean on 151 patients. Inclusion criteria: none stated Exclusion criteria: surgery where a mask was specifically required, e.g. air borne infection Participants were similar at baseline for age, gender, weight, prophylactic antibiotics and ASA classification
Interventions	Group 1. Mask (n = 313) Group 2. No mask (n = 340)
Outcomes	Wound infection defined by criteria used by National Nosocomial Infection Surveillance System: superficial incisional, deep incisional and organ space Group 1. Mean follow-up 33.4 days (SD 22.1) Group 2. Mean follow-up 33.4 days (SD 22.8)
Notes	Missing data for 7 clean cases. Unit of analysis error present. Quote: "Only non-scrubbed staff, including anaesthetists, were asked to comply with the random assignment." Comment: scrubbed staff were not included in the trial

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Random sequence generation (selection bias)	Low risk	Quote: "Operating lists were randomised into two arms, mask group and no mask group using a computer-generated randomisation schedule." Comment: This precaution reduces the risk of selection bias.
Allocation concealment (selection bias)	Low risk	Quote: " Allocation occurred immediately before the commencement of the session, following a phone call to a person who was unaware of the type of list in each theatre". Comment: this precaution reduces the risk of selection bias
Blinding (performance bias and detection bias) Blinding patient	Low risk	Patients were unaware of treatment allocation
Blinding (performance bias and detection bias) Blinding outcome assessor	Low risk	Quote: "Details about any post operative wound infection was obtained by routine surveillance methods, that is by the medical officer, ward staff or infection control nurse who were blinded to the treatment protocol."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Clean data not analysed on an intention-to-treat basis; 7 drop-outs reported
Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported on, but trial protocol not accessed
No bias due to source of funding?	Low risk	Quote: "JW received grant support through two Queensland Health Nursing Research Grants." Comment: this grant is unlikely to have biased the results of the trial
No bias due to early stopping?	Low risk	The trial was based on a power calculation and was not stopped early
No bias due to baseline comparability of treatment and control groups	Low risk	Groups were comparable for baseline characteristics of type of surgery, wound and ASA classification as well as age, gender, preoperative hospitalisation, weight and prophylactic antibiotics

ASA: American Society of Anaesthesiologists
SD: standard deviation

Characteristics of excluded studies [ordered by study ID]

Jump to: **scolaris.cdsr.references.jump.to.included.studies**

Study	Reason for exclusion
Alwitry 2002	The measurement of bacterial load was used rather than infection rates
Berger 1993	The study was concerned with both contamination and wound infection. It was poorly designed as all procedures had varying mask positions at different times of the procedure. It was impossible to distinguish from the results the masked and unmasked periods. Settle plates were used to measure contamination and no infections were recorded. This study was discontinued after recruitment of 30 patients due to the unacceptable level of contamination of the settle plates.
Ha'eri 1980	This study was primarily concerned with surgical site contamination by human albumen microspheres and not surgical wound infection
Hubble 1996	Excluded as it was a theatre-based simulation that did not involve any surgery. Contamination was measured using settle plates at various distances from the participant. This study included hats as well as masks in traditional and laminar flow theatres.
McGovern 2013	The effect of different surgical gowns on counts of airborne particles was investigated in this study, with the primary outcome being mean particle count (not rate of postoperative surgical wound infection).
McLure 1998	A laboratory simulation involving the analysis of bacterial colonies on agar plates. No surgery was involved.
Mitchell 1991	An operating department simulation, therefore not involving surgery. The study measured the contamination of settle plates as a method of recording bacterial dispersal.
Moore 2001	This study investigated the use of visors against masks. There were no surgical episodes where the surgical team's faces were uncovered. The surgical site infection rate was calculated on the outcome of a patient questionnaire. The subjective nature of these results meant that the study could not be used in the review.
Norman 1995	The use of visors and masks by staff was compared for acceptability and contamination. A group not wearing either mask or visor was not included.
Orr 1981	Excluded as it was not possible to distinguish how many clean operations were included in the study. Contact attempted with author.
Ritter 1975	This study was concerned with contamination of the environment rather than surgical site infection. Settle plates were used during non-operating period.
Ruthman 1984	The study examined the use of a cap and a mask in an Accident and Emergency department. These 2 variables could not be differentiated.
Salassa 2014	The study is not a randomised controlled trial; it is a review.

Study	Reason for exclusion
Sjol 2002	Stated as a RCT, but this study was observational and followed up patients for surgical wound infections post-discharge via a questionnaire.
Tunevall 1992	This study took place during actual operations but the specific outcome measure of the study was contamination of settle plates. Although it was reported that no surgical site infections occurred during the study period, the cross-over design of the study meant that all patients were exposed to a masked and non-masked period. The authors therefore could not utilise the results of this study.

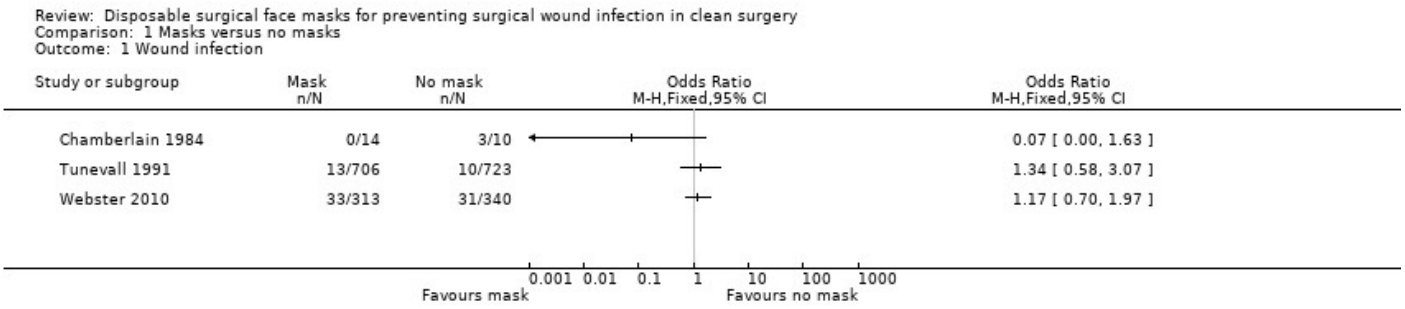
ASA classification: the American Society of Anaesthesiologists physical status classification system is a system for assessing the fitness of patients before surgery
RCT: randomised controlled trial
SSI: surgical site infection

Data and analyses

Comparison 1. Masks versus no masks — **Open in table viewer**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Wound infection **Show forest plot**	3		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected

Analysis 1.1 — **Open in figure viewer**


Review: Disposable surgical face masks for preventing surgical wound infection in clean surgery
Comparison: 1 Masks versus no masks
Outcome: 1 Wound infection
Study or subgroup
Mask n/N
No mask n/N
Odds Ratio M-H,Fixed,95% CI
Odds Ratio M-H,Fixed,95% CI
Chamberlain 1984 0/14 3/10 0.07 [0.00, 1.63]
Tunevall 1991 13/706 10/723 1.34 [0.58, 3.07]
Webster 2010 33/313 31/340 1.17 [0.70, 1.97]
0.001 0.01 0.1 1 10 100 1000
Favours mask
Favours no mask

Comparison 1 Masks versus no masks, Outcome 1 Wound infection.

Information

DOI:

https://doi.org/10.1002/14651858.CD002929.pub3 Copy DOI Check for updates

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Cochrane Database of Systematic Reviews

Version published:

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Collapse

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Contributions of authors

Peggy Edwards identified studies from the initial search and selected studies independently for data extraction, devised the data extraction sheet, independently extracted the data from studies, drafted the protocol and the review jointly with Allyson Lipp, provided content expertise and agreed with the update of the review.

Marina Vincent undertook the seventh update of this review, screened the search output and updated the text and plain language summary.

Contributions of editorial base

Nicky Cullum: edited the review, advised on methodology, interpretation and review content. Approved the final review and review update prior to submission.
Sally Bell-Syer: co-ordinated the editorial process. Advised on methodology, interpretation and content. Edited the review and the updated review.
Ruth Foxlee: designed the search strategy, ran the searches and edited the search methods section for previous updates.
Rachel Richardson: checked previous review updates prior to submission.
Reetu Child: ran the searches and checked the search strategy for this update.

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Declarations of interest

Marina Vincent: none known.
Peggy Edwards: none known.

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Allyson Lipp was the originator of this review and was responsible for the development of the protocol, the review and all updates to the present time. She has now retired and has stepped away from her author role. We would like to acknowledge her substantial involvement in this systematic review.

What's new

Date	Event	Description

Date	Event	Description
1 April 2016	New citation required but conclusions have not changed	Seventh update; no change to conclusions; no new studies added.
1 April 2016	New search has been performed	New search.

History

Protocol first published: Issue 4, 2000
Review first published: Issue 1, 2002

Date	Event	Description
29 October 2013	New search has been performed	Sixth update.
29 October 2013	New citation required but conclusions have not changed	New search; no new studies identified; no change to conclusions.
19 January 2010	New search has been performed	New search; one additional trial included (Webster 2010); no change to conclusions. Clarification of participants being the patients undergoing surgery not the members of the surgical team wearing the face mask.
18 June 2008	Amended	Converted to new review format.
4 February 2008	New search has been performed	For this third update new searches were carried out in February 2008. No new relevant studies were identified. The authors' conclusions remain unchanged. Published in *The Cochrane Library*, Issue 2, 2008.
10 February 2006	New search has been performed	For the second update new searches were carried out in February 2006. One new study was identified (Alwitry 2002), but was excluded from the review. Published in *The Cochrane Library*, Issue 3, 2006.
16 April 2004	New search has been performed	For the first update, new searches were carried out in April 2004. One new study was identified (Sjol 2002), but was excluded from the review. Published in *The Cochrane Library*, Issue 3, 2004.

Date	Event	Description
20 November 2001	New citation required and conclusions have changed	Substantive amendment.

Version history

Title	Stage	Authors	Version	Publication Date
Disposable surgical face masks for preventing surgical wound infection in clean surgery	Review	Marina Vincent, Peggy Edwards	https://doi.org/10.1002/14651858.CD002929.pub3	26 April 2016
Disposable surgical face masks for preventing surgical wound infection in clean surgery	Review	Allyson Lipp, Peggy Edwards	https://doi.org/10.1002/14651858.CD002929.pub2	17 February 2014
Disposable surgical face masks for preventing surgical wound infection in clean surgery	Review	Allyson Lipp, Peggy Edwards	https://doi.org/10.1002/14651858.CD002929	21 January 2002

What's new

Date	Event	Description
1 April 2016	New citation required but conclusions have not changed	Seventh update; no change to conclusions; no new studies added.
1 April 2016	New search has been performed	New search.

Appendices

Appendix 1. Search strategies

The Cochrane Wounds Specialised Register

#1 (mask or masks or facemask or facemasks or "face mask" or "face masks") AND (INREGISTER)
#2 (surg* NEAR5 (infect* or wound* or site* or incision* or dehisc*)) AND (INREGISTER)
#3 (wound* NEAR5 (infect* or site* or dehisc* or disrupt)) AND (INREGISTER)
#4 (wound NEXT complication*) AND (INREGISTER)
#5 #2 OR #3 OR #4
#6 #1 AND #5

The Cochrane Central Register of Controlled Trials (CENTRAL)

#1 MeSH descriptor: [Masks] explode all trees
#2 ("mask" or "masks" or facemask or facemasks or "face mask" or "face masks"):ti,ab,kw
#3 #1 or #2
#4 MeSH descriptor: [Surgical Wound Infection] explode all trees
#5 MeSH descriptor: [Surgical Wound Dehiscence] explode all trees
#6 (surg* near/5 infection*):ti,ab,kw
#7 (surg* near/5 wound*):ti,ab,kw
#8 (surg* near/5 site*):ti,ab,kw
#9 (surg* near/5 incision*):ti,ab,kw
#10 (surg* near/5 dehisc*):ti,ab,kw
#11 (wound* near/5 dehisc*):ti,ab,kw
#12 (wound* near/5 infect*):ti,ab,kw
#13 (wound near/5 disruption*):ti,ab,kw
#14 (wound next complication*):ti,ab,kw
#15 {or #4-#14}
#16 #3 and #15 in Trials

Ovid MEDLINE

1 exp Masks/
2 (mask*1 or facemask or face mask*).tw.
3 or/1-2
4 exp Surgical Wound Infection/
5 exp Surgical Wound Dehiscence/
6 (surg* adj5 infect*).tw.
7 (surg* adj5 wound*).tw.
8 (surg* adj5 site*).tw.

9 (surg* adj5 incision*).tw.
10 (surg* adj5 dehisc*).tw.
11 (wound* adj5 dehisc*).tw.
12 (wound* adj5 infect*).tw.
13 (wound adj5 disrupt*).tw.
14 wound complication*.tw.
15 or/4-14
16 3 and 15
17 randomized controlled trial.pt.
18 controlled clinical trial.pt.
19 randomi?ed.ab.
20 placebo.ab.
21 clinical trials as topic.sh.
22 randomly.ab.
23 trial.ti.
24 or/17-23
25 exp animals/ not humans.sh.
26 24 not 25
27 16 and 26

Ovid EMBASE

1 exp face mask/
2 (mask*1 or facemask or face mask*).tw.
3 or/1-2
4 exp surgical infection/
5 exp wound dehiscence/
6 (surg* adj5 infect*).tw.
7 (surg* adj5 wound*).tw.
8 (surg* adj5 site*).tw.
9 (surg* adj5 incision*).tw.
10 (surg* adj5 dehisc*).tw.
11 (wound* adj5 dehisc*).tw.
12 (wound* adj5 infect*).tw.
13 (wound adj5 disrupt*).tw.
14 wound complication*.tw.
15 or/4-14
16 3 and 15
17 Randomized controlled trials/
18 Single-Blind Method/
19 Double-Blind Method/
20 Crossover Procedure/

21 (random$ or factorial$ or crossover$ or cross over$ or cross-over$ or placebo$ or assign$ or allocat$ or volunteer$).ti,ab.
22 (doubl$ adj blind$).ti,ab.
23 (singl$ adj blind$).ti,ab.
24 or/17-23
25 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/
26 human/ or human cell/
27 and/25-26
28 25 not 27
29 24 not 28
30 16 and 29

EBSCO CINAHL Plus

S29 S16 AND S28
S28 S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27
S27 MH "Quantitative Studies"
S26 TI placebo* or AB placebo*
S25 MH "Placebos"
S24TI random* allocat* or AB random* allocat*
S23 MH "Random Assignment"
S22 TI randomi?ed control* trial* or AB randomi?ed control* trial*
S21 AB (singl* or doubl* or trebl* or tripl*) and AB (blind* or mask*)
S20 TI (singl* or doubl* or trebl* or tripl*) and TI (blind* or mask*)
S19 TI clinic* N1 trial* or AB clinic* N1 trial*
S18 PT Clinical trial
S17 MH "Clinical Trials+"
S16 S3 AND S15
S15 S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14
S14 TI wound complication* or AB wound complication*
S13 TI wound* N5 disrupt* or AB wound* N5 disrupt*
S12 TI wound* N5 infect* or AB wound* N5 infect*
S11 TI wound* N5 dehisc* or AB wound* N5 dehisc*
S10 TI surg* N5 dehisc* or AB surg* N5 dehisc*
S9 TI surg* N5 incision* or AB surg* N5 incision*
S8 TI surg* N5 site* or AB surg* N5 site*
S7 TI surg* N5 wound* or AB surg* N5 wound*
S6 TI surg* N5 infect* or AB surg* N5 infect*
S5 (MH "Surgical Wound Dehiscence")
S4 (MH "Surgical Wound Infection")
S3 S1 or S2

S2 TI (mask* or facemask* or face mask) or AB (mask* or facemask* or face mask*)
S1 (MH "Masks")

Appendix 2. Risk of bias definitions

1. Was the allocation sequence randomly generated?

Low risk of bias

The investigators describe a random component in the sequence generation process such as: referring to a random number table; using a computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots.

High risk of bias

The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number.

Unclear

Insufficient information about the sequence generation process to permit judgement of low or high risk of bias.

2. Was the treatment allocation adequately concealed?

Low risk of bias

Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomisation); sequentially numbered drug containers of identical appearance; sequentially numbered, opaque, sealed envelopes.

High risk of bias

Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

Unclear

Insufficient information to permit judgement of low or high risk of bias. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement, for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and

sealed.

3. Blinding - was knowledge of the allocated interventions adequately prevented during the study?

Low risk of bias

Any one of the following.

- No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

High risk of bias

Any one of the following.

- No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding.
- Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.

Unclear

Any one of the following.

- Insufficient information to permit judgement of low or high risk of bias.
- The study did not address this outcome.

4. Were incomplete outcome data adequately addressed?

Low risk of bias

Any one of the following.

- No missing outcome data.
- Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.

- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size.
- Missing data have been imputed using appropriate methods.

High risk of bias

Any one of the following.

- Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size.
- 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

Unclear

Any one of the following.

- Insufficient reporting of attrition/exclusions to permit judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided).
- The study did not address this outcome.

5. Are reports of the study free of suggestion of selective outcome reporting?

Low risk of bias

Any of the following.

- The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
- The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon)

High risk of bias

Any one of the following.

- Not all of the study's pre-specified primary outcomes have been reported.
- One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified.
- One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect).
- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis.
- The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Unclear

Insufficient information to permit judgement of low or high risk of bias. It is likely that the majority of studies will fall into this category.

6. Other sources of potential bias

Low risk of bias

The study appears to be free of other sources of bias.

High risk of bias

There is at least one important risk of bias. For example, the study:

- had a potential source of bias related to the specific study design used; or
- had extreme baseline imbalance; or
- has been claimed to have been fraudulent; or
- had some other problem.

Unclear

There may be a risk of bias, but there is either:

- insufficient information to assess whether an important risk of bias exists; or
- insufficient rationale or evidence that an identified problem will introduce bias.